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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/641,742 | 08/18/2000 | Samuel J. Danishefsky | 2003080-0054 | 7338 |

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| EXAMINER | |
|---|---|
| CANELLA, KAREN A | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1643 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/641,742 | DANISHEFSKY ET AL. | |
| | Examiner | Art Unit | |
| | Karen A. Canella | 1643 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *56,58-62,65-67,69-76,78-81,84-86 and 88-102* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *56,58-62,65-67,69-76,78-81,84-86 and 88-102* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

**DETAILED ACTION**

Claims 72, 85, 91, 96 have been amended. Claims 99-102 have been added. Claims 56, 58-62, 65-67, 69-76, 78-81, 84-86 and 88-102 are pending and under consideration.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

The rejection of claims 56, 58-62, 65, 67, 69-71, 73-76, 78-81, 84, 86, 88-90, 92-95, 97 and 98 under 35 U.S.C. 102(e) as being anticipated by Danishefsky et al (U.S. 6,660,714) is maintained for reasons of record.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Danishefsky et al discloses the instant glycoconjugates having a peptide backbone made up of at least three amino acids, wherein each occurrence of $R_D$, $R_E$ and $R_F$ is independently a carbohydrate domain that includes the instant polysaccharides (see claim 6 of '714, for example) Danishefsky et al disclose carriers of BSA, polylysine, KLH, tripalmitoyl-S-

glycerylcysteinylserine and compositions comprising bacterial adjuvants such as BCG, Salmonella minnesota and QS21 which is a saponin (see claims 51, 52, 56 and 57). The disclosure of glycopeptides comprising independent carbohydrate domains encompasses glycopeptides having different carbohydrate domains for $R_D$, $R_E$ and $R_F$, which is commensurate with having multiple carbohydrate domains. Danishefsky et al teach the cross linker of claim 65 (see columns 17-18). Thus the disclosure of the '714 patent encompasses constructs which comprises independent carbohydrate domains that are not identical and thus anticipates the instant claims for a multi-antigenic construct..

Applicant has submitted a Declaration under 37 CFR 1.132 to aver that the invention disclosed but not claimed in the '714 reference was derived from the inventors of the instant application and is thus not invented "by another". This argument fails to overcome the instant rejection because the invention of the '714 reference is claimed, rather than disclosed but not claimed (claims 6, 51, 52, 56).

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned

with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 56, 58, 59, 60-62, 65, 69-71, 73-76, 78-81, 84, 86, 88-90, 92-95, 97 and 98 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-47 of U.S. Patent No. 7,160,856. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '856 patent anticipate the instant claims.

Claims 56, 58-62, 65-67, 69-76, 78-81, 84-86 and 88-102 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 118-129, 132-146, 148-199 of copending Application No. 10/209,618 and claims 1-47 of copending Application No. 10/728,041. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the reference applications anticipate the instant claims..

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 56, 58-62, 65, 67, 69-71, 73-76, 78-81, 84, 86, 88-90, 92-95, 97 and 98 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-58 of U.S. Patent No. 6,660,714. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to the products and compositions used in the method claims of the '714 patent. Thus the instant claims are obvious over the method claims of the patent.

Claims 56, 58-62, 65, 67, 69-71, 73-76, 78-81, 84, 86, 88-90, 92-95, 97 and 98 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-47 of U.S. Patent No.7,160,856. Although the conflicting claims are not identical,

they are not patentably distinct from each other because the claims of the patent include multiantigenic constructs because the carbohydrate domains are independently selected from Tn, sTn, sT, etc (see claim 3 of '856).

All other rejections and objections as set forth or maintained in a prior Office action are withdrawn.

All claims are rejected.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Cong et al (U.S. 7,018,637) suggests that carbohydrate fragments such as Globo H, Le-y or sTn be incorporated into multivalent molecules having a peptide backbone (abstract, figures 2A and 2B and columns 11-12 under "Multiple antigenic peptide approach"). However, Chong et al fail to teach the glycosidic moiety attached via an ether linkage to a methylene.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Karen A Canella/
Primary Examiner, Art Unit 1643